

MICHAEL J. GARCIA
United States Attorney for the
Southern District of New York
By: TOMOKO ONOZAWA
SERRIN TURNER
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2721 (Onozawa)
(212) 637-2701 (Turner)
Facsimile: (212) 637-2686
E-mail: tomoko.onozawa@usdoj.gov
serrin.turner@usdoj.gov

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X	
NICOLE EBON,	:
	:
Plaintiff,	:
	:
-against-	:
	:
UNITED STATES OF AMERICA,	:
	:
Defendant.	:
	:
-----X	

ECF CASE
08 Civ. 0144 (AJP)
**GOVERNMENT'S PRE-TRIAL
MEMORANDUM**

Defendant the United States of America (the "Government"), by its attorney, Michael J. Garcia, United States Attorney for the Southern District of New York, respectfully submits this memorandum to summarize briefly the facts and law applicable to this case.

STATEMENT OF FACTS

On January 2, 2004, plaintiff Nicole Ebron ("plaintiff"), 35 years of age, went to the Parkchester Family Practice ("Parkchester") at 1597 Unionport Road, Bronx, New York for a routine physical examination. That day, she was seen by her primary care physician, Dr. Eric Gayle, M.D. ("Dr. Gayle"), and Bettie Laverne Gilmore, L.P.N. ("Nurse Gilmore"), both

employees of Parkchester. During the examination, Dr. Gayle advised plaintiff to have a Tetanus-diphtheria vaccination, because her last vaccination was in 1993, and also ordered that plaintiff's blood be drawn for a routine blood test.

Dr. Gayle verbally informed plaintiff of the known risks of receiving the tetanus vaccination—namely, redness or soreness at the site. Nurse Gilmore also informed plaintiff of the known side effects of the tetanus vaccine (symptoms of redness, heat, and swelling at the site of the injection) and provided her with a copy of a two-page information sheet “Tetanus and Diphtheria Vaccine (Td)” prepared by the Centers for Disease Control of the U.S. Department of Health and Human Services. As defendants' experts will testify, because it is common knowledge that breaking the skin for any procedure—whether for routine blood draws or for any kind of vaccination—runs a small risk of introducing bacteria into the body, neither Doctor Gayle nor Nurse Gilmore was required to inform plaintiff that the act of piercing the skin with a needle can cause a bacterial infection.

Nurse Gilmore administered both the blood draw and the vaccination. Contrary to plaintiff's contention, there was a sufficient supply of alcohol swipes in plaintiff's examination room at Parkchester. Thus, before drawing a blood sample and administering the tetanus shot on plaintiff's left arm, Nurse Gilmore used alcohol swipes to sterilize both sites. Consistent with the known side effects of the tetanus vaccine, between January 3, 2004 and January 11, 2004, plaintiff experienced redness, heat, swelling and pain at the site of the injection. By her own admission, plaintiff periodically rubbed and touched the site of the injection.

On January 12, 2004, plaintiff returned to Parkchester with complaints of pain, swelling, and burning at the site of the injection. According to her medical records, she also stated that the band-aid that covered the injection site caused her to have a reaction and made her skin peel.

Upon examination, Dr. Gayle observed that the skin was red, peeling, warm, and tender, and diagnosed plaintiff with a skin infection called cellulitis. He advised plaintiff to apply warm compresses to the area, to take Tylenol for the pain, and prescribed Biaxin, an antibiotic.

On January 13, 2004, plaintiff went to the emergency room of Jacobi Medical Center (“Jacobi”) in Bronx, New York. At this time, plaintiff was found to have an abscess over the left deltoid muscle around the site of the injection that required surgical incision and drainage and yielded 15 cc of purulent material. Plaintiff’s wound was covered with Iodoform gauze, and she received a sling for her arm. She also received local wound instructions, and prescription for Percocet and tetracycline, that was to replace her previous prescription for Biaxin.

On January 21, 2004, plaintiff returned to Parkchester for a follow-up appointment for her skin infection. According to plaintiff’s medical record of that visit, plaintiff told Nurse Gilmore that her arm “feels much better.” Dr. Gayle then examined plaintiff’s arm and observed that she had an 0.5-cm open wound that was clean, had no drainage or tenderness, and was healing well. During this visit, Dr. Gayle explained to plaintiff that when the skin is broken by an injection, it can sometimes cause an infection. Dr. Gayle also discussed the possibility that plaintiff had suffered an allergic reaction to the band-aid covering the site, and added that plaintiff’s application of alcohol to the site could have contributed to the problem by drying out and irritating the skin.

Plaintiff’s other medical records will show that she visited Jacobi approximately five times between January 13, 2004, and late March 2004. Medical records from Jacobi further show that, during plaintiff’s last visit in March 2004, she was told that her wound was healing well, and that no further medical treatment was necessary.

The evidence will show that plaintiff currently has a well-healed, 0.4-centimeter non-tender, nodular scar at the site of the injection. The Government's expert testimony will further show that she has a full range of motion in all joints, as well as normal sensation and strength, and that there is no objective evidence of any functional limitation to plaintiff's arm as a result of the scar. Although plaintiff claims to suffer periodic "shooting pains" in the same arm as a result of the injection, she has never sought medical attention for those symptoms, nor received any medical diagnosis for the problem.

ARGUMENT

A. Liability

Plaintiff brought this action under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 1346(b), which provides for exclusive federal jurisdiction over claims against the United States for money damages for injury "caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b). Under the FTCA, the substantive law governing tort actions against the United States is the law of the state where the alleged acts or omissions occurred. *Id.* Accordingly, the issues in this action are governed by New York law.

Here, plaintiff's complaint alleges three causes of action grounded in medical malpractice: (1) Nurse Gilmore failed to sterilize the site of the injection before giving the shot because Parkchester ran out of alcohol swipes that day; (2) Dr. Gayle and Nurse Gilmore failed to inform plaintiff of the known risks of receiving the vaccination; and (3) Dr. Gayle improperly prescribed Tylenol and Biaxin, an antibiotic, when plaintiff returned to Parkchester on January

12, 2004, with symptoms of redness, peeling, warmth, tenderness, and induration at the site of the injection, and was diagnosed with cellulitis of the arm. Plaintiff cannot prove all three claims by a preponderance of the evidence.

1. Dr. Gayle and Nurse Gilmore Informed Plaintiff of the Known Risks of Receiving the Tetanus Vaccination

To prevail on her cause of action based on lack of informed consent, plaintiff must prove by a preponderance of the evidence: “(1) that [the] medical provider failed to disclose alternatives thereto and failed to inform the patient of reasonably foreseeable risks associated with the treatment, and the alternatives, that a reasonable medical provider would have disclosed in the same circumstances, (2) that a reasonably prudent patient in the same position would not have undergone the treatment if he or she had been fully informed, and (3) that the lack of informed consent is a proximate cause of the injury.” *Johnson ex rel. Johnson v. Columbia Univ.*, No. 99 Civ. 3415 (GBD), 2003 WL 22743675, at *16 (S.D.N.Y. Nov. 19, 2003). Under New York law, risks “too commonly known to warrant disclosure” need not be disclosed. N.Y. Pub. Health Law § 2805-d(4)(a). Under New York law, a plaintiff making an informed consent claim also must “adduce expert medical testimony in support of the alleged qualitative insufficiency of the consent.” N.Y.C.P.L.R. § 4401-a.

As set forth in the Government’s Motion *In Limine* to Preclude Certain Evidence, plaintiff’s informed consent claim fails because her expert’s report is devoid of any opinion regarding what a reasonable medical practitioner under the circumstances here would have disclosed. Plaintiff also cannot meet her burden of proving lack of informed consent by a preponderance of the evidence. The evidence will show that Dr. Gayle and Nurse Gilmore properly informed plaintiff of the known risks of receiving the tetanus vaccination, both verbally

and by providing her with a copy of the CDC information sheet that listed the benefits and risks of the tetanus vaccination. It was acceptable practice for Dr. Gayle and Nurse Gilmore to not inform plaintiff that breaking the skin with a medical instrument could lead to a bacterial infection. While rare, bacterial infections are a known risk or complication of any breach of skin by any medical instrument. As a result, as the Government's experts will testify, it is not routine practice for patients to be counseled about the risk of infection from a break in the skin during a vaccination. Furthermore, to the extent plaintiff's claim for lack of informed consent is premised on Nurse Gilmore's alleged failure to inform her that administering a shot without disinfecting the site first can lead to a bacterial infection, that claim should be dismissed as duplicative of her medical malpractice claim. The doctrine of informed consent addresses a doctor's failure to inform a patient of the reasonably foreseeable risks of *professional treatment or diagnosis*—not the reasonably foreseeable risks of committing malpractice. *See* N.Y. Pub. Health Law § 2805-d. Otherwise, every act of malpractice would automatically include a claim for lack of informed consent as to that act of malpractice.

2. Nurse Gilmore Cleaned the Site of the Tetanus Vaccination With An Alcohol Swipe

To prevail in a medical malpractice action under New York law, plaintiff must prove: “(1) that the defendant breached the standard of care in the community, and (2) that the breach proximately caused the plaintiff's injuries.” *Milano by Milano v. Freed*, 64 F.3d 91, 95 (2d Cir. 1995) (quoting *Arkin v. Gittleson*, 32 F.3d 658, 664 (2d Cir.1994)). Proximate cause is established where an alleged deviation from the standard of care was a “substantial factor” in producing the injury. *See Greenfield v. Memorial Sloan Kettering Hosp.*, No. 95 Civ. 7658 (KTD), 2000 WL 351395, at *5 (S.D.N.Y. Apr. 15, 2000). Most importantly, defendant cannot

be found liable in this case “solely for a poor result.” *Jones v. United States*, No. 83 Civ. 6785, 1986 WL 1459, at *4 (S.D.N.Y. Jan. 28, 1986). New York law further provides that expert medical opinion testimony is required to prove both elements of medical malpractice. *See Sitts v. United States*, 811 F.2d 736, 739-40 (2d Cir. 1987).

The parties agree that failure to cleanse the site of an injection before administering a vaccination deviates from the standard of care in the relevant medical community. However, plaintiff cannot offer any objective evidence to corroborate her claims that Parkchester ran out of alcohol swipes that day, and that Nurse Gilmore failed to clean the site of the injection with a disinfectant before administering the tetanus vaccination. Her contention that Nurse Gilmore found only *one* alcohol swipe in the examination room—which was used to sterilize the site of the blood draw—but could not find a second alcohol swipe for the tetanus shot, is implausible. In contrast, the evidence will show that, by plaintiff’s own admission, she touched and rubbed at the site of the tetanus shot with her hands several times between January 3 and January 11, or may have scratched at the site due to peeling and irritation from an allergic reaction to the Band-aid covering the site, and/or her application of alcohol to the site.

3. Dr. Gayle Prescribed the Appropriate Medications for Plaintiff on January 12, 2004

As for plaintiff’s third cause of action, plaintiff’s expert report is devoid of any opinion that Dr. Gayle, when he prescribed Biaxin and Tylenol for plaintiff on January 12, 2004, deviated from the accepted standard of care in the relevant medical community, and that the alleged deviation proximately caused plaintiff’s injury. As a result, plaintiff’s third claim must fail because New York law provides that expert medical opinion testimony is required to make out both elements of medical malpractice. *See Sitts v. United States*, 811 F.2d 736, 739-40 (2d

Cir. 1987). Moreover, as the Government's experts will testify, Biaxin is an acceptable and appropriate choice for cellulitis in patients with documented allergies to penicillin and/or penicillin-like drugs. Plaintiff has a documented allergy to penicillin.

B. Damages

In addition to showing that plaintiff's injury is not attributable to any negligence on defendant's part, the evidence will also show that plaintiff is entitled, at most, to modest damages for pain and suffering. As a preliminary matter, plaintiff cannot prove, by a preponderance of the evidence, any of her past and future medical expenses, and past and future out-of-pocket expenses. Plaintiff has admitted under oath that she has neither produced nor is in possession of any documents supporting those amounts, and lacks personal knowledge as to how these estimates were made. Plaintiff has also admitted under oath that she has never consulted with any medical professional regarding the potential cost to correct the scar, and has no documents demonstrating the cost of such surgery. Plaintiff therefore is not entitled to any damages for past or future medical care. *See Mickens v. LaSala*, 779 N.Y.S.2d 115, 117 (2d Dep't 2004) ("damages cannot be based on mere speculation, conjecture, or surmise").

In addition, there is no objective evidence of any impairment or functional limitation to plaintiff's arm as a result of the scar. As the Government's expert will confirm, his physical examination of her confirmed nothing more than a 0.4-centimeter, well-healed, nodular scar on her left arm that is otherwise unremarkable. Plaintiff has also never sought any medical or mental-health consultations for her subjective claims of physical and emotional pain.

CONCLUSION

The evidence will show that plaintiff cannot meet her burden of proof and that the Government is entitled to judgment in this matter.

Dated: New York, New York
September 9, 2008

MICHAEL J. GARCIA
United States Attorney for the
Southern District of New York
Attorney for Defendant

By: /s/ Tomoko Onozawa
TOMOKO ONOZAWA
SERRIN TURNER
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2721 (Onozawa)
(212) 637-2701 (Turner)
Facsimile: (212) 637-2686
E-mail: tomoko.onozawa@usdoj.gov
serrin.turner@usdoj.gov